REMARKS

This document is in response to the Examiner's communication dated November 19, 2007 (the Office Action) and the Notice of Non-Compliant Amendment dated July 25, 2008 (the Notice). This document is also a summary of the telephone interviews conducted between the Examiner Tongue and Dr. Fahrni on July 29, 2008 and July 31, 2008.

Claims 1-22 are pending. By this Amendment, claim 2 is cancelled, claims 1, 3, 4, and 12 are amended. Claim 1 is amended to delete certain embodiments of the application. The original limitation from claim 2 is amended into claim 1. Claim 3 is amended to delete certain embodiments of the application. Dependent claims 4 and 12 are amended in view of the amendment in claim 1. Claim 12 is further amended in accordance with the agreement reached between Dr. Fahrni and Examiner Tongue.

Interview between Examiner Tongue and Dr. Fahrni

Dr. Fahrni requested an interview with Examiner Tongue to discuss how to appropriately respond to the Notice. During the interview, Dr. Fahrni inquired about the possibility of keeping claim 12 for future examination. Examiner Tongue requested the Applicants to amend claim 12 to be commensurate in scope with independent claim 1 so it could be examined together with the other elected claims. Claim 12 has been amended accordingly. The Applicants thank Examiner Tongue for allowing amended claim 12 to be included for future examination.

Restriction Requirement

Claims 1, 2, 4, 6, 7, and 10-12 are elected. Claims 3, 5, 8, 9, and 13-22 are withdrawn from further consideration as being drawn to non-elected inventions. Applicants maintain that claim 1 is a linking claim for claims 5-12 and 20-22, such that rejoinder of non-elected claims 5, 9, and 20-22 is requested upon such time as claim 1 is allowed. Elections are made for procedural purposes and no admissions are made with respect to patentability or claims construction. Additionally, the Applicants maintain the traversal of the Restriction Requirement to preserve the right of petition.

Information Disclosure Statement

An information disclosure statement is submitted with this reply. As outlined in the section below relating to 35 USC § 102, Braun et al. (2004) is submitted as evidence that only a limited number of *Moraxella catarrhalis* strains has LOS with oligosaccharides showing cross-reactivity with *Neisseria meningitidis* and human blood group antigens.

35 U.S.C. §112

I. The Examiner rejected claims 1, 2, 4, 6, 7, 10, and 11 under 35 U.S.C. §112, first paragraph that the application does not sufficiently enable people with ordinary skill in the art to use the invention. Applicants assume the Examiner intended to reject claims 1, 2, 4, 6, 7, and 10-12. Applicants respectfully disagree with this rejection.

It is well-settled that a therapeutic method need not be ready for clinical application in order to be enabled. See In re Brana, 51 F.3d 1560, 1567, 34 USPQ2d 1436, 1442 (Fed. Cir. 1995): "Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans." In general, the references cited by the Examiner are directed to a different therapeutic problem and are not applicable, as explained below. Further, the amended claims are drawn much more narrowly and are believed to address the Examiner's concerns. This rejection is traversed, however, on the grounds that there is no prima facie case of nonenablement.

Breadth of the Claims

The Examiner states that the claims are broadly drawn. The claims, however, are directed specifically to the treatment or prevention of diseases due to infection by *Neisseria meningitidis.* As outlined on page 1, lines 16 to 20 of the application, there are only two forms of meningococcal disease, which are meningitis and septicaemia. The therapeutical indication in claim 1 is directed to specific and highly related conditions so that it is believed to be drawn narrowly and not broadly.

Additionally, the medicament of claim 1 comprises purified lipooligosaccharides from commensal *Moraxella catarrhalis,* the oligosaccharide portion of which being cross-reactive to

Neisseria meningitidis of serogroup B and cross-reactive to human blood group antigens. The selection of oligosaccharides of LOS with the concrete cross-reactivity renders claim 1 very specific, because only some *Moraxella catarrhalis* strains have LOS oligosaccharides which are cross-reactive with *Neisseria meningitidis* and human blood group antigens. The amended claims have been specifically drawn to only serogroup B to thereby eliminate about 12 antigens and further reduced to claim lipooligosaccharides and therefore are believed to address concerns about undue breadth.

Directions or Guidance Presented in the Specification

The Applicants discovered that LOS from *Moraxella catarrhalis*, more specifically the oligosaccharides of the LOS, are cross-reactive antigens to *Neisseria meningitides* and human blood group antigens and can be useful as a medicament for the treatment or prevention of infection by *Neisseria meningitides*.

The application provides sufficient information to people with ordinary skill in the art on how to obtain these LOS from *Moraxella catarrhalis*. On page 22, lines 21 to 31 of the application, a method for the extraction of the LOS is disclosed. As noted by the Examiner on page 7 of the Office Action, the application provides working examples from pages 51 to 55, showing how to determine cross-reactivity between *Moraxella catarrhalis*, *Neisseria meningitides* and human blood group antigens. People with ordinary skill in the art in view of the application could obtain *Moraxella catarrhalis* LOS with the required cross-reactivity by obtaining strains of *Moraxella catarrhalis* and checking whether they have the necessary cross-reactivity.

As noted on page 7 of the Office Action, it is shown in the application that the antibodies against the oligosaccharide portion of LOS of *Moraxella catarrhalis* with the specified cross-reactivity are bactericidal, opsonising and neutralizing antibodies. Additionally, the antibodies are anti-inflammatory. The effects are demonstrated in a mouse model and with human serum (Table 19). The data shows that the antibodies are functional but do not adversely affect the patient. In meningococcal disease, the finding that the medicament induces non-inflammatory, bactericidal, opsonising and neutralizing antibodies is substantive evidence that the medicament is functional. Accordingly, in contrast to the statement of the Examiner on page 7 of the Office

Action, the Applicants provided substantive evidence that the claimed composition is capable of inducing protective immunity against infection by *Neisseria meningitides*. People with ordinary skill in the art therefore can expect that the medicament confers protective immunity.

On page 7 of the Office Action, the Examiner compares the inventive antibodies to antibodies against HIV-1, which can induce neutralizing antibodies but not protection. Further, on page 9 of the Office Action, the Examiner refers to Boslego et al., showing that although a high level of serum antibody response is induced, a gonococcal pillin protein does not elicit immunity. Respectfully, the Applicants would like to point out that HIV-disease and gonococcal disease have totally different pathogenic mechanisms compared to meningococcal disease. The comparison of antibodies from HIV-disease and gonococcal disease with the antibodies from the present application is therefore not appropriate. Viral infections like HIV are chronic and intracellular. In a chronic intracellular viral infection, it is obvious that neutralizing antibodies can not provide protection to the same extent. Similarly, an antibody against a pillin protein as described by Boslego et al. is not immunogenic and can at best reduce the adherence, but not the invasion. Unlike in the present application, the antibodies of Boslego et al. do not destroy the cause of the infection.

In contrast, in meningococcal disease, the acute and major damage to the host is mediated by the inflammatory response to the LOS. Consequently, the recognition of the LOS by antibodies directly targets the LOS and the bacteria. In view of the specific mechanism of meningococcal disease, people with ordinary skill in the art would appreciate that the vaccine induces anti-inflammatory, neutralizing, bactericidal and opsonising antibodies, and therefore would understand that the antibodies are powerful vaccines, which can be used in the treatment of a meningococcal disease in passive immunisation. Indeed, the antigens are, in fact, powerful vaccines for active immunisation. Since the vaccine of the application is shown to be highly effective and not causing inflammation, the skilled person can administer it to a patient. This does not require any undue experimentation.

Presence or Absence of Working Examples

The application includes a large number of detailed working examples showing, amongst